Syneron

Medical LTD

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JUN 11 2012

# 510(K) SUMMARY

## ePlus Skin Treatment System

## 510(k) Number K113868

**Applicant's Name:** Syneron Medical Ltd.
Industrial Zone
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Yokneam Illit 20692
Israel
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**Contact Person:** Yoram Levy, Qsite
31 Haavoda Street
Binyamina, Israel 30500
Tel (972)4-638-8837; Fax (972)4-638-0510
Yoram@qsitemed.com

**Trade Name:** ***ePlus Skin Treatment System***

**Preparation Date:** December 27, 2011

**Classification:** **Name**: Powered laser surgical instrument
**Product Code:** GEX, OUH
**Regulation No:** 21 CFR 878.4400, 21CFR 878.4810
**Class:** II
**Panel:** General and Plastic Surgery

**Device Description:**

The ***ePlus skin treatment system*** is a multi-application system that provides a variety of skin treatments. The system combines Syneron's previously cleared Polaris, Aurora and eTwo treatment Systems and their applicators. The ***ePlus skin treatment system*** delivers two ranges of electromagnetic energy to the skin tissue through the system applicators:

1. Optical radiation through Laser or IPL (Intense Pulse Light) in the visible & near-IR range.
2. RF current conducted through the tissue at 1MHz

**Intended Use Statement:**

The ***ePlus Skin Treatment system*** is intended for dermatological procedures.

The **DS** applicator is indicated for the removal of unwanted hair from skin types I-VI, and to effect stable long-term, or permanent, hair reduction*.

The **DSL** applicator is indicated for hair removal, permanent hair reduction*. The applicator is intended for use on all skin types, (Fitzpatrick skin type I-VI), including tanned skin.

The **LV** applicator is indicated for treatment of vascular lesions.

The **LVA** applicator is indicated for treatment of vascular lesions.

The **WRA** applicator is indicated for non invasive wrinkles treatment.

The **SR** applicator is intended for superficial benign vascular and pigmented lesion treatment such as:
lentigines, freckles, telangiectasia, rosacea, poikiloderma, angioma, sun spots and age spots.
The **SR** treatment may be performed on body areas such as the face, chest, hands and arms. It can be also performed on sporadic lesions anywhere on the body.

The **SRA** applicator is intended for superficial benign vascular and pigmented lesion treatment such as:
lentigines, freckles, telangiectasia, rosacea, poikiloderma, angioma, sun spots and age spots.
The **SRA** treatment may be performed on body areas such as the face, chest, hands and arms. It can be also performed on sporadic lesions anywhere on the body.

The **AC** applicator is indicated for the treatment of moderate inflammatory acne vulgaries.

The **Sublative RF** applicator is indicated for Dermatological procedures requiring ablation and resurfacing of the skin, and for the treatment of facial wrinkles.

The **Sublime** applicator is indicated for non invasive wrinkles treatment.

**Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regimen*

**Predicate Devices**: Substantial equivalence to the following predicate devices is claimed:

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| Syneron Device Name | 510k No | Date of Clearance |
|---|---|---|
| **Polaris DS / Comet Applicator** | K041959 | November 8, 2004 |
| **Polaris LV** | K030186 | April 14, 2003 |
| **Polaris WR** | K031671 | December 1, 2003 |
| **Aurora SR** | K031993 | August 1, 2003 |
| **AC applicator, Aurora AC** | K032514 | January 27, 2004 |
| **Aurora DS, DS applicator** | K050796 | April 12, 2005 |
| **Aurora SR and SRA applicator** | K050452 | March 9, 2005 |
| **Polaris LV, LVA applicator** | K052324 | September 14, 2005 |
| **eTwo Skin Treatment System** | K110672 | October 03, 2011 |

**Performance Standards:**

***ePlus Skin Treatment System*** complies with:

- IEC 60601-1 : "Medical Electrical Equipment" Part 1: "General requirements for safety"
- IEC 60601-2-2: "Medical Electrical Equipment" Part 2: "Particular requirements for the safety of high frequency surgical equipment" (2006)
- IEC 60601-2-22 : "Medical Electrical Equipment" Part 2: "Particular requirements for the safety of diagnostic and therapeutic laser equipment" (1995)
- IEC60825-1 : Safety of laser products Part 1: "Equipment classification, requirements and user's guide" (2007)
- IEC 60601-1-2 Ed. 2.1 (2004): medical electrical equipment: Part 1-2 collateral standard: Electromagnetic compatibility – Requirements and tests"

A detailed description appears in **Section 13**.

**Summary of Clinical Performance Data:**

The safety and efficacy of the ***ePlus Skin Treatment System*** was evaluated in the clearance process of the predicate devices that use the same applicators that are part of this device. Syneron believes that clinical data is not required to determine the safety and efficacy of the ***ePlus Skin Treatment System*** since the intended use and technical performance of ePlus and its applicators are equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 1 1 2012

Syneron, Ltd
c/o Qsite
Yoram Levy
31 Haavoda Street
Binyamina, Israel 30500

Re: K113868
Trade/Device Name: ePlus Skin Treatment System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: June 01, 2012
Received: June 05, 2012

Dear Yoram Levy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

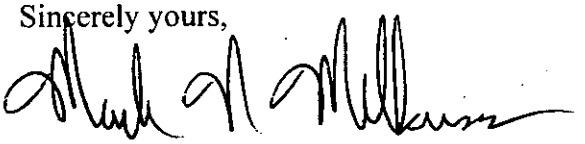
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Syneron
Medical LTD

# INDICATIONS FOR USE STATEMENT

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Neil R. Ogden for mxn
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113868

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lentigines, freckles, telangiectasia, rosacea, poikiloderma, angioma, sun spots and age spots.
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**Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regimen*

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-off)
Division of General, Restorative and Neurological Devices
510(k) Number

for mxm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113868